REMARKS

These remarks are in response to the Office Action mailed March 26, 2003. Claims 11, and 12 have been amended. Claims 14-17 have been added. Support for the amended claims and new claims can be found throughout the specification. For example, support for the recitation of "95% identical to the amino acid sequence set forth in SEQ ID NO:2" as set forth in new claim 16 can be found at page 10, lines 17-21, of the specification. In addition, support for the recitation of "50 conservative amino acid substitutions" as set forth in new claim 17 can be found at page 10, lines 1-16, of the specification. No new matter has been added. Claims 11-119 are pending and at issue. Applicants request reconsideration of the present application.

I. REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Written Description

Claims 11-13 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Applicants traverse this rejection as it may apply to the amended claims.

Claim 11 has been amended to recite, in part, a polypeptide encoded by a polynucleotide that specifically hybridizes to a DNA comprising the nucleotide set forth in SEQ ID NO:1 under highly stringent conditions of washing in 0.1 x SSC. Claim 11 has been further amended to recite a polypeptide having an amino acid sequence at least 80% identical to the amino acid sequence set forth in SEQ ID NO:2. The polypeptide is further defined as comprising the activity of a D-aminoacylase that acts on N-acetyl-D-amino acids to produce the corresponding D-amino acids. Finally, the polypeptide is defined as possessing specifically enumerated physicochemical properties on specific substrates.

Applicants submit that the USPTO policy regarding written description analysis is set forth the "Revised Interim Written Description Guidelines" published January 5, 2001. Example 9 of the guidelines analyzes a claim directed to an isolated nucleic acid that hybridizes to a particular disclosed sequence and encodes a protein having a particularly specified activity.

When analyzing the claimed genus encompassed by the claim, the PTO concludes that "a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claims yield structurally similar DNAs. Thus, a representative number of species [namely, the molecule consisting of SEQ ID NO.1], is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that Applicant was in possession of the claimed invention."

As previously noted, the polypeptides of claim 11, part (c), are limited to those encoded by a polynucleotide that "specifically hybridizes to a DNA comprising the nucleotide sequence set forth in SEQ ID NO:1 under highly stringent conditions of washing in 0.1 x SSC." The polypeptides of claim 11, part (d), are limited to those having an amino acid sequence at least 80% identical to the amino acid sequence set forth in SEQ ID NO:2. The polypeptides of claim 11, parts (c) and (d), are further limited to specifically enumerated physicochemical properties (i.e., acts on one of the specifically enumerated N-acetyl-D-amino acid substrates to produce the corresponding D-amino acids). In light of the amendments to the claims, and in view of the written description guidelines established by the Office, Applicants submit that those skilled in the art would believe that Applicants were in possession of the claimed invention as of the filing date sought.

Accordingly, Applicants request that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

Enablement

Claims 11-13 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter not described in the specification in such a way as to enable one of skill in the art to make or use the invention. Applicants traverse this rejection as it may apply to the amended claims.

The enablement decision tree set forth in the "Training Materials For Examining Patent Applications With Respect To 35 USC 112, First Paragraph- Enablement Chemical/Biotechnical Applications" first asks the question: "Does the specification teach how to make and use at least one embodiment encompassed by the claims as a whole without undue experimentation?"

Applicants not only provide general guidance as to how to make and use embodiments of the claimed invention but also describe a representative species that falls within the scope of the claimed invention (i.e., the protein of SEQ ID NO:2).

The second question in the enablement decision tree is: "Are the enabled embodiments representative of the full scope of the claim?" As discussed above, the PTO itself has deemed a single disclosed species to be representative of the genus of homologues claimed under these circumstances, since a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions and the high degree of homology set forth in the claims yield structurally similar polypeptides.

Applicants have disclosed amino acid sequences (i.e., structure) of a novel polypeptide having aminoacylase activity. At the time the present application was filed, the state of the art and level of skill of the ordinary artisan in the field of molecular biology was advanced. Thus, one of ordinary skill in the art can use well-known laboratory techniques such as library screening, and with modifications such as using the amino acid structure to create degenerate probes / promoters, probe custom-made or commercially available libraries for polynucleotides that hybridize to the probes (or are amplified by the primers). These polynucleotides can be expressed by known methods to obtain polypeptides. The polypeptides can be tested to see if they meet the requirements to be one of the claimed polypeptide, i.e., 80% identical to SEQ ID NO:2, and having aminoacylase activity with specific physicochemical properties. The exemplary protocol is provides in the application, and this is basically how the novel enzyme was discovered. Accordingly, based on the Applicants' disclosure, the claimed invention is properly enabled for one skilled in the art to practice the invention. It would be a matter of routine experimentation, not undue experimentation, for one skilled in the art to find polypeptides at least 80% identical to SEQ ID NO:2 or 80% identical to SEQ ID NO:6 and having D-aminoacylase activity.

Regarding undue experimentation, the Federal Circuit in In re Wands directed that the focus of the enablement inquiry should be whether the experimentation needed to practice the invention is undue. Applicants submit that the written disclosure of the instant application is supplemented by the knowledge held by one of ordinary skill in the art. The skilled artisan is

one who is knowledgeable about basic laboratory/research protocols. It is well settled law that an Applicant need not include disclosure that was well known in the art. Furthermore, in addition to the knowledge held by the skilled artisan, Applicants provide an exemplary basic methodology for obtaining polypeptides of the invention, i.e., the method disclosed in the application used to obtain the polypeptide encoding the novel enzyme. It is well within the capabilities of the skilled artisan, at the time the application was filed, to take such teachings and modify the protocol, for example, the probe, library, and/or conditions, to obtain polypeptides of the invention. Thus, the specification provides sufficient guidance for one of ordinary skill in the art to practice the claimed invention.

Applicants respectfully submit that the application, at the time of filing, taught one of skill in the art how to make and use the claimed invention. Accordingly, in light of the above, Applicants request reconsideration and withdrawal of the rejection of claims 11-13 under 35 USC §112, first paragraph.

II. Rejections under 35 USC §112, second paragraph

Claims 11-13 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to recite an essential step. Specifically, the Office Action states that the claims omit the step of isolating and purifying the produced D-amino acid. While Applicants traverse this rejection, claim 11 has been amended to include a second step directed to "isolating and purifying the D-amino acid produced by the reaction between said polypeptide and said N-acyl-DL-amino acid" in order to expedite prosecution. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claims 11-13 under 35 USC §112, second paragraph,

III. Rejections under 35 USC §102(a)

Claims 11-13 stand rejected under 35 USC 102(a) as allegedly anticipated by Tokuyama (EP '057). Applicants traverse this rejection as it may apply to the amended claims.

The Office Action states that the cited reference teaches a D-aminoacylase and method for producing D-amino acids using said D-aminoacylase. Applicants submit that Tokuyama fails to teach a method of producing a D-amino acid using: 1) a polypeptide comprising SEQ ID

NO:2; 2) a polypeptide consisting of SEQ ID NO:2; 3) a polynucleotide that specifically hybridizes to a DNA comprising the nucleotide sequence set forth in SEQ ID NO:1 under highly stringent conditions of washing in 0.1 x SSC; 4) a polypeptide having an amino acid sequence at least 80% identical to the amino acid sequence set forth in SEQ ID NO:2; or 5) a polypeptide comprising the amino acid sequence set forth in SEQ ID NO:2 with up to 50 conservative amino acid substitutions. The methods claimed in the present application are clearly not anticipated by the cited reference because the D-aminoacylase disclosed by Tokuyama is distinct from that utilized in the methods of claims 11, 14, 15, 16, 17, 18 and 19. Thus, the Tokuyama reference fails to disclose each and every element of the claimed invention. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claims 11-13 under 35 USC 102(a).

In summary, for the reasons set forth herein, Applicants maintain that claims 11-19 clearly and patentably define the invention. Applicants request that the Examiner reconsider the various grounds set forth in the Office Action and allow the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicants' representative can be reached at (858) 678-5070. Enclosed is a $336 check for excess claims fee and a $410 check for the Petition for 2 month Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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